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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,465	10/19/2000	Peter Kufer	147-199P	3425

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/23/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/554,465

Applicant(s)

KUFER ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 4/10/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-24, and 27-29 drawn to a method of using *polypeptide* product identifying a binding site domain having capacity of binding to a predetermined epitope in a recombinant bi or multivalent polypeptide in a biological display system.

Group II, claims 1-24 and 27-29, drawn to a method of using *antibody* products identifying a binding site domain having capacity of binding to a predetermined epitope in a recombinant bi or multivalent polypeptide in a biological display system.

Group III, claims 1-26, drawn to a method of using *polynucleotides* encoding the said antibodies or polypeptides and cells transfected with the said polynucleotides identifying a binding site domain having capacity of binding to a predetermined epitope in a biological display system.

The invention listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Polypeptides are generally known to be smaller than proteins and also do not possess the structural characteristics of antibodies. Similarly, polynucleotides have the distinct characteristics and properties not sharing by either polypeptides or antibodies. Therefore, there is lack of unity of inventive concept among peptides, antibody and polynucleotides.

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2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

If elect invention of Group I, applicants requires to elect *one* sequence of *polypeptide*.

If elect invention of Group II, applicant requires to elect *one* sequence of *antibody*.

If elect invention of Group III, applicants needs to elect *one nucleotide* sequence.

### ***Response to Applicant's Argument***

2. Applicant argues that the US Office should be consistent with the lack unity practice by other International Search Authority, not just by giving "verbal assent to lack of unity by mere reference to the PCT rule, but rather an actual application of the standard." (See Remarks page 2, third paragraph) The examiner agrees, in part. The examiner would like to point out that the previous Office Action requested on Restriction/Election is not a "mere reference to PCT Rule". The examiner had outlined different groups based on the special technical features, and cited the prior art, and the application against the inventive concept of this current application. The practice of this Office handling PCT case should be consistent with the PCT examiner on the same subject matter under same rule. Nevertheless, should inadvertence or misjudging occurred during the International Stage Examination, this Office is not bound to comply with the obvious errors.

3. With respect to the argument on the McGuinness et al. reference (Natural Biotechnology (1996) 14: 1149) The examiner agrees with the applicant's argument that the said reference does not render the instant application not novel. Accordingly, the examiner withdraws the requirement of restriction set forth in the previous Office Action, and regrouped the current invention into Group I, II and III based on the special technical features of the polypeptide, antibody and polynucleotides as discussed above.

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4. In response to this Office Action, applicant **MUST** elect one group with an elected **ONE** species for examination.

5. The examiner notices that claims 22 and 24 do not recite proper SEQ ID No. in compliance with the Sequence Rule. Please provide the proper SEQ ID No. for the purposes of examination.

6. Applicant's IDS filed on 10/19/2000 is received by this Office on record. However, the IDS is missing. Please submit a new copy of IDS with the response to this Office Action. The examiner apologizes for any inconvenience.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner



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March 20, 2004



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

03/20/04